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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/598,671

09/07/2006

Michael Martin

20674-0008US1

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EXAMINER

PAK, JOHN D

ART UNIT

PAPER NUMBER

1616

NOTIFICATION DATE

DELIVERY MODE

07/22/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATDOCTC@fr.com

Office Action Summary	Application No. 10/598,671	Applicant(s) MARTIN, MICHAEL	
	Examiner John Pak	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 May 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) 11 and 18-29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 and 12-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>9/06, 2/07</u> . | 6) <input type="checkbox"/> Other: _____ |

Claims 1-29 are pending in this application.

Applicant's election without traverse of the invention of Group I in the response filed on 5/4/2010 is acknowledged.

Claims 11 and 18-29 are withdrawn from further consideration as being directed to non-elected subject matter. Claims 1-10 and 12-17 will presently be examined to the extent that they read on the elected subject matter of record, i.e. method of reducing severity of inflammation in a subject by administering an effective amount of lithium chloride.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-10, 12-17 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 98/17288.

WO 98/17288 explicitly discloses administering lithium chloride over a period of 2 to 10 weeks to a human subject to combat human papilloma virus infection. See claims 5, 7, 9-11; page 8, third full paragraph; page 10, first and second full paragraphs. The human subject can be infected or not yet infected (i.e. at-risk). See claim 6.

All of applicant's claim language are so imprecisely presented that they are all deemed to be anticipated by the cited prior art disclosure. Claims 2-4 recite a timing feature relative to contact with "an inflammatory agent" or beginning of inflammation. These features are met by any human subject, who is under constant exposure to various bacterial, viral and other inflammatory agents from ordinary environmental conditions. Claims 5-9 recite various types of infections, but the subject of WO 98/17288 meets applicant's "subject with inflammation or at risk for inflammation." In claim 12 the inflammation is sepsis, but it must be recognized that claim 12 reads on a subject who is at risk for sepsis. In the absence of a clear definition of what is meant by a subject who is at risk for sepsis (how much risk?), the subject of WO 98/17288 is deemed to read on the claimed subject. Claims 13 and 14 recite lithium chloride administration prior to or after surgery and prior to or after contact with an infectious biological weapon, respectively. Again, in light of the "at risk" claim scope and lack of preciseness as to timing (what does "prior" cover?), the method and subject in WO 98/17288 are deemed to meet claims 13 and 14. Claims 1, 15 and 16 recite specific mechanism by which lithium chloride inhibits GSK-3 activity, but since the subject in WO 98/17288 has been administered the same exact lithium chloride, the same effect would necessarily have been obtained in that subject.

For these reasons, elected and examined subject matter in claims 1-10 and 12-17 are found anticipated.

Applicant is advised that the listing on the IDS of 9/7/2006 was crossed out because there is a duplicate listing on the IDS of 2/9/2007.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to JOHN PAK whose telephone number is **(571)272-0620**. The Examiner can normally be reached on Monday to Friday from 8 AM to 4:30 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's SPE, Johann Richter, can be reached on **(571)272-0646**.

The fax phone number for the organization where this application or proceeding is assigned is **(571)273-8300**.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571)272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/John Pak/
Primary Examiner, Art Unit 1616